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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,241	10/19/2001	Darrell C. Conklin	00-94	7880

7590 03/29/2005

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,241	CONKLIN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-11,14 and 26-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-11, 14, and 26-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed November 24, 2004 is acknowledged and has been entered. Claims 1, 2, 5, 8, and 26-29 have been amended. Claims 33 and 34 have been added.

2. Claims 1-3, 5-11, 14, and 26-34 are pending in the application and are currently under prosecution.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Grounds of Objection and Rejection Withdrawn

5. Unless specifically reiterated below, Applicant's amendment and/or arguments filed November 24, 2004 have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed June 2, 2004.

Grounds of Objection and Rejection Maintained

Specification

6. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Applicant has attempted to resolve this issue by amending the specification to properly demarcate the recited trademarks that were provided as examples in the previous Office action; however, additional examples of improperly demarcated trademarks appear in the specification, including, for example, Affymetrix™ (page 103, line 31).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Objections

7. Claim 31 is objected to because "expression" is misspelled as "epression". Notably, this is a new issue raised by the amendment filed November 24, 2004, as "expression" was correctly spelled in the immediate prior version of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. The rejection of claims 1-3, 5-11, 14, and 26-34 under 35 U.S.C. § 101, because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility, is maintained.

This ground of rejection is set forth in section 9 of the Office action mailed June 2, 2004, beginning at page 3.

At pages 12-15 of the amendment filed November 24, 2004, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The considerations that are made in determining whether a claimed invention is supported by either a specific and substantial asserted utility or a well-established utility are outlined by the published Utility Examination Guidelines (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: http://www.gpoaccess.gov/.

Briefly, a "specific and substantial" asserted utility is an asserted utility that is specific to the particular nature and substance of the claimed subject matter, and which would be immediately available for application in a "real-world" context by virtue of the existing information disclosed in the specification and/or on the basis of knowledge imparted by the prior

art, such that its use would not require or constitute carrying out further research to identify or reasonably confirm its usefulness in this context. A "well-established" utility is a credible, specific, and substantial utility, which is well known, immediately apparent, and implied by the specification, and based on the disclosure of the properties of a material or subject matter, either alone or taken with the knowledge of one skilled in the art.

Beginning at page 12 of the amendment, Applicant has argued that the claimed polynucleotides can be used as probes. Any nucleic acid molecule can be used as a probe. A nucleic acid molecule will hybridize to itself; therefore, the nucleic acid molecule can be used as probe to detect its presence in a sample. Because any nucleic acid can be used in this manner, this asserted utility is not specific to the chemical and biologic nature of the claimed invention, itself; rather, it is a utility that is generically applicable to its class of molecule.

Applicant has argued that the claimed polynucleotides can be used to detect duplications of chromosome 7. Chromosome 7 is a very large molecule comprising literally millions and millions of basepairs. In fact, according to the website of the National Center of Biotechnology of the U.S. National Library of Medicine, which is available on the Internet at http://www.ncbi.nlm.nih.gov/genome/guide/human, the chromosome comprises approximately 158 megabasepairs (158×10^{12} basepairs). The polynucleotide sequence of the cDNA molecule isolated by Applicant represents a minute small part of chromosome 7. As any substantial part of chromosome 7 could be used to assess the duplication of chromosome 7, it is submitted that the asserted utility of the claimed invention is not a specific utility. Moreover, the asserted utility does not depend upon the specific chemical and biologic nature of the polynucleotide or the protein(s) that is encoded by the sequence; in fact, one could use the claimed invention as disclosed as such a probe without having any other information regarding the specific nature and function of the polynucleotide sequence or the protein(s) encoded thereby. Furthermore, the claimed polynucleotide has not been shown to be associated with any particular disease or disorder, or any specific aberration of chromosome 7. Therefore, it is submitted that asserting that the claimed invention is useful as a probe for determining whether chromosome 7 has been duplicated is a utility that can be generically applied to countless other polynucleotides contained within the structure of chromosome 7 and tantamount to a "throw-away" or "insubstantial"

utility, which the Utility Examination Guidelines (*supra*) indicates are excluded from "specific and substantial" utilities.

As explained in the previous Office action, the instant application provides a description of a polynucleotide sequence, which putatively encodes a protein. The protein, which has the predicted amino acid sequence set forth in SEQ ID NO: 2, is what is termed in the art, an "orphan protein". This is a protein that is encoded by a complementary DNA (cDNA) molecule, which has been isolated by virtue of its having a polynucleotide sequence having similarity to other known cDNA molecules, which Applicant originally gleaned by "scanning" a database of polynucleotide sequences. The observed similarity between the polynucleotide sequences, or the putative amino acid sequences encoded thereby often leads to speculation that the protein will be found to have a particular function. In this instance, the polynucleotide sequence encoding SEQ ID NO: 2 is similar to polynucleotide sequences encoding cytokines. Indeed, it is not unlikely that after further characterization the protein of SEQ ID NO: 2, which is encoded by the claimed polynucleotides, will be found to have a specific utility. However, until the further characterization of the protein encoded by the newly discovered polynucleotide sequence has been completed establishing the protein's putative function, the polynucleotide sequence is only a novelty and therefore not a finished invention having an established utility.

The instant situation is directly analogous to that which was addressed in *Brenner, Comr. Pats. v. Manson,* 148 U.S.P.Q. 689 (U.S. Sup. Ct., 1966). A novel compound, which was found to be structurally analogous to other compounds known to possess anti-cancer activity, was alleged to be useful by virtue of its structural similarity to these other useful compounds but otherwise, in the absence of factual evidence. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The Court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. Id., at 695.

Further, the Court opined,

> [W]e are [not] blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. Id., at 696.

Accordingly, as the instant claims are drawn to polynucleotides that encode polypeptides of, as yet, an undetermined function or biological significance, until some actual and specific significance can be attributed to the polypeptide of SEQ ID NO: 2, or *Zlmda24,* as it is named in the disclosure, the inventive process has not been refined or developed to a point where a specific benefit can be derived by the public from the granting of a patent upon the Applicants' application. Moreover, in the absence of any established functional or biological significance, there is no immediately obvious "patentable" use for the claimed invention. To employ the claimed polynucleotide in any of the manners asserted, which would be specific to the chemical and biologic nature of the claimed invention, as opposed to generically applicable to its class of molecule, would clearly require further research, which should be regarded as constituting part of the inventive process. Because the specification does not disclose a currently available, "real world" use for the claimed polynucleotide, the requirements set forth under 35 U.S.C. § 101 have not been met.

The existing information disclosed by Applicants' application would merely provide the artisan with an invitation to perform such investigations, which might ultimately lead to a derivation of a specific benefit, or which might not; and in either case, an immediate benefit could not be derived from the use of the claimed invention because the existing information is insufficient to enable the artisan to use the claimed polynucleotide in the manner asserted to provide an immediate benefit. Although the disclosure of the claimed polynucleotide might tomorrow command the grateful attention of the public, the Court has decided:

> [A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

Brenner, Comr. Pats. v. Manson, 148 U.S.P.Q. 689 at 696 (US SupCt, 1966).

At page 14, Applicant has further argued that the claimed invention "finds" utility in histological applications. However, Applicant has not explained how the claimed invention can be used in a specific and substantial manner in a "histological application".

Furthermore, Applicant has argued the claimed invention can be used to produce a protein, which can be used to produce an antibody that binds that protein. This utility is not a specific and substantial utility for the reasons addressed here and in the previous Office action.

In summary, where Applicant has argued the claimed invention has practical use, the asserted utilities are not specific. Where the asserted utilities would be specific, the asserted utilities lack the required practicality and are therefore not specific *and* substantial utilities, because the invention could not be used immediately in such manners to achieve a result that is beneficial to the public, as the inventive process has yet to be completed to that point.

Claim Rejections - 35 USC § 112

9. The rejection of claims 1-3, 5-11, 14, and 26-34 under 35 U.S.C. 112, first paragraph is maintained. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth in section 9 above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's traversal of this ground of rejection is acknowledged and has been considered, but this ground of rejection is maintained together with the ground of rejection under 35 U.S.C. § 101 for the reasons set forth above.

10. The rejection of claims 11, 14, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This ground of rejection is set forth in section 12 of the Office action mailed June 2, 2004, beginning at page 3.

At pages 15 and 16 of the amendment filed November 24, 2004, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

As explained in the previous Office action at page 11, broadly interpreted, claims 11, 14, and 32 are directed to a method for producing any member of a genus of fusion proteins or polypeptides produced by the cultured cells of claims 10, 7, and 31, respectively. However, the specification merely describes the polypeptide of SEQ ID NO: 2, which is encoded by the claimed nucleic acid molecules of SEQ ID NO: 1 and SEQ ID NO: 5. Because the specification does not describe the other fusion proteins or polypeptides produced by the cultured cells of claims 7, 10, and 32, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Applicant has argued that the invention would be understood and that it is not necessary to teach that which is understood. In reply, the claims have been given the broadest reasonable interpretation. The claims are not limited to a method for producing the polypeptide or fusion protein comprising an amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 32 to amino acid number 253. The members of the genus of polypeptides and fusion proteins that are produced by the host cells are not adequately described or represented by the polypeptide of SEQ ID NO: 2.

This issue can be remedied by amending claims 11, 14, and 32 to recite that the polypeptide that is produced and isolated by the claimed processes is the polypeptide or fusion protein comprising an amino acid sequence as shown in SEQ ID NO: 2 from amino acid number 32 to amino acid number 253.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2001/0053519 A1.

Claim 34 is drawn to an isolated polynucleotide comprising at least 14 contiguous nucleotides of the polynucleotide sequence set forth as SEQ ID NO: 1 or its complement, which hybridizes to human chromosome 7 at 7q21 under specified hybridization wash conditions.

A polynucleotide comprising 14 or more contiguous nucleotides of the polynucleotide sequence set forth as SEQ ID NO: 1 or its complement hybridizes to human chromosome 7 at 7q21 under specified hybridization wash conditions.

U.S. Patent Application Publication 2001/0053519 A1 "n-mer arrays" comprising a solid support to which are attached all possible nucleic acid sequences of a given length, such as, and including a 25-mer array; see entire document (e.g., page 10, paragraph [0101]).

The n-mer arrays (e.g., the array of 25-mers), which are disclosed by U.S. Patent Application Publication 2001/0053519 A1 and comprise nucleic acid molecules of at least 14 residues, comprise an isolated polynucleotide comprising at least 14 contiguous nucleotides of the polynucleotide sequence set forth as SEQ ID NO: 1 or its complement, which hybridizes to human chromosome 7 at 7q21 under specified hybridization wash conditions.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

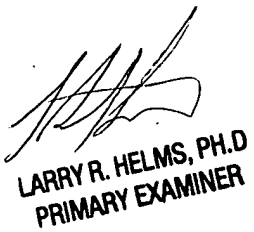
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642



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